

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

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Serial No.: 10/777,310

Confirmation No.: 5538

Filed: 12 February 2004

For: METHOD AND COMPOSITIONS RELATED TO IRM COMPOUNDS AND TOLL-LIKE RECEPTOR 8

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### Remarks

The Office Action mailed 23 August 2007 has been received and reviewed. Claim 21 having been amended and claim 45 having been added, after entry of the amendment, the pending claims are claims 21 and 30-45. Reconsideration and withdrawal of the rejections are respectfully requested.

Claim 21 is the only independent claim. Each of claims 30-45 depends, directly or indirectly, from claim 21 and, therefore, includes all of the features recited in claim 21. Thus, remarks below that refer to claim 21 apply equally to each of claims 30-45.

### Interview Summary

Applicants' representative thanks Examiner Robinson for the courtesy of a telephonic interview held October 18, 2007. Participating on behalf of Applicants were Bryon Merrill and Applicants' representative, Christopher Gram. Applicants discussed the Richardson paper of record and offered an amendment to obviate rejections under 35 U.S.C. §112. Applicants' remarks are summarized below.

Examiner Robinson indicated her willingness to enter Applicants' amendments and stated that the amendments appeared to overcome the cited art and resolve all other issues.

### Claim Amendments

Claim 21 is amended as agreed during the telephonic interview.

Claim 21 is further amended to recite that the pharmaceutical composition can include a pharmaceutically acceptable salt of the recited TLR8 agonists. Support for the amendment can be found in Applicants' disclosure at, for example, page 11, lines 25-30.

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New claim 45 depends from claim 38 and recites a particular TLR8 agonist. The recited compound is identified as IRM3 in Table 1 (page 25-28) and is demonstrated to be a TLR8 agonist in Example 1 (page 28, line 22 through page 30, see Table 2, page 29-30).

No new matter is introduced by these amendments.

**The 35 U.S.C. §112, First Paragraph, Rejection (Written Description)**

Claims 21 and 30-44 stand rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Office Action asserts that the claims are not clearly defined by structural limitations. Applicants respectfully traverse.

Claim 21 recites a pharmaceutical composition comprising a TLR8 agonist that comprises a 2-aminopyridine fused to a five membered nitrogen-containing heterocyclic ring in an amount effective to modulate at least one TLR8-mediated cellular signaling pathway in combination with a pharmaceutically acceptable carrier. During the interview, Applicants explained that the 2-aminopyridine fused to a five membered nitrogen-containing heterocyclic ring structure is a common structural feature of all of the compounds encompassed by the claims as amended herein, thereby providing clearly defined structural features.

Applicants respectfully submit that claims 21 and 30-44 satisfy the written description requirement of 35 U.S.C. §112, first paragraph, and request that the rejection be withdrawn.

**The 35 U.S.C. §112, First Paragraph, Rejection (Enablement)**

Claims 21 and 30-44 stand rejected under 35 U.S.C. §112, first paragraph, as failing to reasonably provide enablement for any or all TLR8 agonists recited in claim 21. Specifically, the Office Action asserts that "the claims do not provide a structure *per se*, as there is no indication in the claims how each compound is associated with each other[.]" (Office Action, page 5-6). Applicants respectfully traverse.

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During the interview, Applicants explained that the compound families previously recited in claim 1—most of which are maintained in dependent claims 30-44—were intended to be subgenera of the genus of compounds having a 2-aminopyridine fused to a five membered nitrogen-containing heterocyclic ring, not substituents that can be added to the ring structure.

Applicants respectfully submit that claims 21 and 30-44 satisfy the enablement requirement of 35 U.S.C. §112, first paragraph, and request that the rejection be withdrawn.

**The 35 U.S.C. §112, Second Paragraph, Rejection**

Claims 21 and 30-44 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Office Action asserts that no nexus is provided that gives a clear picture of structure. Applicants respectfully traverse.

As noted in the immediately preceding sections, Applicants explained the structural connection between the compounds recited in the currently pending claims during the interview.

Applicants respectfully submit that claims 21 and 30-44 satisfy the requirements of 35 U.S.C. §112, second paragraph, and request that the rejection be withdrawn.

**The 35 U.S.C. §102 Rejection**

Claims 21 and 30 stand rejected under 35 U.S.C. §102(b) as being anticipated by Richardson (*J. Org. Chem.*, 1963, vol. 25, p.1138). Applicants respectfully traverse.

During the interview, Applicants explained that Richardson fails to set forth, either expressly or inherently, compounds that include a 2-aminopyridine fused to a five membered nitrogen-containing heterocyclic ring. Therefore, Richardson fails to set forth each and every feature recited in Applicants' claims. Consequently, Richardson cannot anticipate Applicants' claims.

Applicants respectfully submit that claims 21 and 30 are patentable under 35 U.S.C. §102(b) over Richardson and request that the rejection be withdrawn.

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Summary

Applicants respectfully submit that the pending claims 21 and 30-45 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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11/09/2007  
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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 9<sup>th</sup> day of November, 2007, at 11:05 am (Central Time).

By: Dani Moroz  
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